

**PROPOSED DRAFT
FIRST COAST SERVICE OPTIONS
MAC - PART A/B
CODING GUIDELINES**

LCD Database ID Number

DL35931

Contractor Name

First Coast Service Options, Inc.

Contractor Number

09101 - Florida

09201 – PR/USVI

09102-Florida

09202 – Puerto Rico

09302 – Virgin Islands

LCD Title

Humanitarian Use Device (HUD) and Humanitarian Device Exemption (HDE) process

Coding Guidelines

Each FDA-approved HUD is assigned an identification code by the FDA, which enables Medicare contractors to establish special claims processing procedures. Follow the instructions below when submitting a claim for an HDE. Unless explicitly clarified by CMS in writing, an HDE designated device in a study does not have the status of IDE for coverage purposes.

Part A Claims:

When submitting a claim for HDE, follow these special claims processing procedures:

Do not report the HDE number in the IDE field.

Report the HDE number H##### in 'remarks'.

When reporting the charge for the Humanitarian Device

For implants use revenue code 0278

For other services use an appropriate revenue code

DO NOT report revenue code 0624. This code is ONLY used for Investigational Device Exemptions (IDE) clinical trials.

Part B Claims:

When submitting a claim for HDE, follow these special claims processing procedures:

Humanitarian Use Device (HUD) and Humanitarian Device Exemption (HDE) process Part a and B

Physicians who bill electronically must place the HDE number on the 2300 Investigational Device Exemption Number REF Segment, data element REF02 (REF01=LX) of the 837P.

List the CPT code(s) that appropriately describes the service(s) performed; when a Not Otherwise Classified (NOC) code is used, then a description of the services and the device must be entered on line 19.

ICD-9 diagnosis code V70.7 or ICD-10 diagnosis code Z00.6 (in either the primary or the secondary positions)

CT12345678 (8-digit or generic NCT Clinical Trial Number) in CMS-1500 Paper Form Field 19 or on the Electronic Form, 837P-Loop 2300, REF02, REF01=P4 (do not use “CT” on the electronic form)

Comments

N/A

Revision History

Date	Revision
MM/DD/YYYY	Original

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